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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,108	01/15/2002	Stein Ove Doskeland	Q-64374	8288
7590 03/13/2006 Sughrue Mion Zinn Macpeak & Seas 2100 Pennsylvania Avenue N W Washington, DC 20037-3213			EXAMINER YANG, NELSON C	
			ART UNIT 1641	PAPER NUMBER
DATE MAILED: 03/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/831,108	<b>Applicant(s)</b> DOSKELAND ET AL.	
	<b>Examiner</b> Nelson Yang	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-8, 10-14, 21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-8, 10-14, 21, 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 15, 2005 has been entered.

### ***Response to Amendment***

2. Applicant's amendment of claims 2, 3, 5-8, 10-13, 21, 23-27 is acknowledged and has been entered.
3. Applicant's cancellation of claims 9, 22, 28-29 is acknowledged and has been entered.
4. Claims 2-8, 10-14, 21, 23-27 are currently pending.

### ***Rejections Withdrawn***

5. Applicant's arguments, see p.9, filed December 15, 2005, with respect to the rejections under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 2-8, 10-14, 21, 23-27 under 35 U.S.C. 112, second paragraph, has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-8, 10-14, 21, 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al [US 4,554,088] in view of Ward et al [Ward et al, Colorimetric protein phosphatase inhibition assay of laboratory strains and natural blooms of cyanobacteria: comparisons with high performance liquid chromatographic analysis for microcystins, 1997, FEMS Microbiology Letters, 153, 465-473].

With respect to claim 21, Whitehead et al teach a method for isolation of molecules by placing selective bioaffinity adsorbents (first ligand) on magnetic particles to which labeled ligates (second ligand) and nonlabeled ligates will bind, separating the bound ligates from free ligates, and the label measured (column 15, lines 1-45). Whitehead further teach that the ligand /ligates may include enzyme/inhibitors (column 7, lines 25-35). While Whitehead teaches a generic assay for the detection of inhibitors of enzymes, Whitehead fail to specifically teach an assay for an inhibitor is a phosphatase-targeting toxin involving the use of protein phosphatase.

Ward et al, however, teach a colorimetric protein phosphatase inhibition assay for microcystins using protein phosphatases (p.467, col. 1). Ward et al further teach that microcystins are a group of cyclic heptapeptide hepatotoxins capable of being produced by common bloom-forming genera of cyanobacteria (p.465, col.1), and which bind irreversibly to and inhibit protein phosphatases 1 and 2A (p.465, col.2). Ward et al further teach that due to the increased awareness of the hazards presented by these toxins, increasingly sensitive detection methods are required to provide information for the effective management of waters supporting cyanobacterial blooms (p.466, col.1, pg.2).

Therefore, it would have been obvious to one of ordinary skill in the art to have utilized the method of Whitehead et al to detect specific inhibitors such as microcystins, as suggested by Ward et al, by using an enzyme such as a protein phosphatase as the bioaffinity adsorbent, because the method of Whitehead et al is generic with respect to the analytes that can be detected and the specific binding reagents that can be used and one would be motivated to use the appropriate reagents (protein phosphatases) to detect the desired analyte (microcystins).

8. With respect to claims 2-3, Ward et al teach that microcystins are a group of cyclic heptapeptide hepatotoxins capable of being produced by common bloom-forming genera of cyanobacteria (p.465, col.1),

9. With respect to claims 4, 11, Whitehead et al teach that the labeled ligate and nonlabeled ligates compete for binding to the ligand (column 15, lines 28-45). Since Ward et al teach the use of protein phosphatases as the enzymes to detect toxins such as microcystins (p.466, col.1, pgs.2-3), the labeled ligate and nonlabeled ligates would be labeled and nonlabeled microcystins, which are heptapeptide hepatotoxins.

10. With respect to claim 5, Whitehead et al teach that the amount of unlabeled ligand (toxin) can be determined by collecting the ligand-labeled ligand complex and measuring the label, and using a standard curve to determine the amount of unlabeled ligate (toxin) (column 15, liens 35-40).

11. With respect to claim 6, Ward et al suggests that the detection methods are used for potable waters (p. 466, col.1, pg. 2).

12. With respect to claim 7, Whitehead et al teach that the ligates may include antibodies (column 17, liens 45-60).

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13. With respect to claim 8, Whitehead et al teach that microcystins bind irreversibly to and inhibit protein phosphatases 1 and 2A (p. 465, col.2), demonstrating that PP1 and PP2A are equivalent structures known in the art. Therefore, because these two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute for

14. With respect to claim 10, Whitehead et al teach labeled ligate (second ligand) (column 15, lines 10-15) which would contain a label (reporter moiety).

15. With respect to claim 12, the microcystins to be detected include microcystin-LR (p.465, col.2).

16. With respect to claim 13, Whitehead et al teach ligands coupled to an insoluble support or matrix (column 17, lines 20-30).

17. With respect to claim 14, Whitehead et al teach magnetic particles (column 7, lines 5-15).

18. With respect to claims 23-24, Whitehead et al teach that the bioaffinity adsorbents are bound to the particles covalently (column 7, lines 36-45) or through silane linkages (column 7, lines 45-55).

19. With respect to claim 25, Whitehead et al teach that the labeled ligate is measured directly (column 15, lines 38-40).

20. With respect to claim 26, Whitehead et al teach that competitive assays may be run with labeled ligand and unlabeled ligate (second ligand) (column 15, lines 11-15), which would result in the unlabeled ligate being determined indirectly.

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21. With respect to claim 27, Whitehead et al teach competitive assays in which the amount of bound measurable label is inversely proportional to the amount of analyte in solution (column 8, lines 25-40).

***Response to Arguments***

22. Applicant's arguments with respect to claim 2-8, 10-14, 21, 23-27 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner  
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3/3/06